DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

December 18, 2000

Our Reference: 2915575

Richard Matsu, Executive Vice President
Marukai Corporation
2310 Kamehameha Highway
Honolulu, Hawaii 96819-4531

WARNING LETTER

Dear Mr. Matsu:

We inspected your seafood firm on June 23, 2000. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your dried shaved bonito and dried shaved tuna to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with Mr. Kozaburo Matsu, Vice President, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your ready reference. Your serious HACCP violations are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for dried shaved bonito and dried shaved tuna from [redacted] to ensure control of the food safety hazards of histamine formation, and potential pathogen growth and toxin formation from inadequate drying of the products.

2. You must implement an affirmative step to ensure that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for dried shaved bonito and dried shaved tuna from [redacted] for controlling the food safety hazards of histamine formation and pathogen growth and toxin formation from time/temperature abuse and inadequate drying of the products.

3. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm failed to maintain sanitation control records that, at a minimum, document the monitoring and corrections that are appropriate to the plant and food being processed, and relate to the following:

a) Safety of the water that comes in contact with food or food contact surfaces, or is used in the manufacture of ice;
b) Condition and cleanliness of food contact surfaces;
c) Prevention of cross-contamination from insanitary objects to food, food packaging material and other food contact surfaces;
d) Maintenance of hand washing, hand sanitizing, and toilet facilities;
e) Protection of food, food packaging material, and food contact surfaces from adulterants;
f) Proper labeling, storage, and use of toxic compounds;
g) Control of employee health conditions; and
h) Exclusion of pests from the food plant.

We observed similar deficiencies during the previous inspection of your facility on August 6, 1998. We discussed these deficiencies with Mr. Kozaburo Matsu, Vice President, at the conclusion of the inspection and also reported them by correspondence to him from this office on October 8, 1998. Our recent inspection showed that your firm has not made the corrections.

The above violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure, injunction, or detention of future shipments without physical examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response, documentation such as copies of product specifications, verification plans, your foreign processors' HACCP plans, or other useful information that would assist us in evaluating your corrections. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Dennis K. Linsley
Director
San Francisco District

Enclosure

cc: Kozaburo Matsu, Vice President